

**Remarks**

I. *Introduction*

Claims 1, 3 – 6, and 20 – 25 are pending. Claims 1, and 3 – 6 have been amended. Claims 20 – 25 are new. Claims 11 – 18 have been withdrawn from consideration. Claims 2, 7 – 10, and 19 have been cancelled without prejudice or disclaimer. Applicant reserves the right to pursue the subject matter of these cancelled claims in one or more continuing applications.

Support for the amendments to claim 1 can be found on page 1, lines 25 – 30 and in original claim 2. Support for the amendments to claim 4 may be found on page 2, lines 7 – 9. Support for new claims 20, 21, 22, 23, 24, and 25 can be found in original claims 1, 3, 7, 8, 9, and 10 respectively.

II. *The objection to the drawings should be withdrawn*

The Patent Office has objected to the drawing for the reasons set forth on page 2 of the Office Action. Applicant submits herewith an amended drawing on a Replacement Sheet, thus overcoming the objection to the drawing. Reconsideration and withdrawal of the objection are respectfully requested.

III. *The specification*

On page 3 of the Office Action, the Patent Office has set forth the “preferred layout” for the specification. Although the specific headings set forth on page 3 of the Office Action do not appear on the instant specification, Applicant offers that the instant specification substantially comports with 37 C.F.R. § 1.77(b).

IV. *The claim objections set forth on page 4 of the Office Action should be withdrawn*

On page 4 of the office action the Patent Office has objected to claim 1 because of certain informalities. Applicant offers that the amendments to claim 1 overcome the objection to claim 1. For example, claim 1 no longer recites “comprising with.” Further, claim 1 recites that the flowable component flows down a planar surface. Reconsideration and withdrawal of the objections to claim 1 are respectfully requested.

V. *The rejections under 35 U.S.C. § 112, second paragraph should be withdrawn*

The Patent Office has rejected claims 1 – 10 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. For the reasons set forth below, Applicant offers that the rejections of those claims have either been overcome or have been rendered moot as a result of, *e.g.*, claim cancellations.

As an initial matter, Applicant offers that the rejection of claims 2 – 10, for their use of the phrase “characterized in” has been rendered moot because those claims no longer recite the offending phrase. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection of those claims at least on that basis.

A. Claim 1

On pages 4 and 5 of the Office Action, the Patent Office has rejected claim 1 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Patent Office states that the terms “bio-reagent,” “complimentary bio-reagent,” and “high density” are vague and indefinite. Applicants respectfully disagree.

As an initial matter, part of the rejection of claim 1 under 35 U.S.C. § 112, second paragraph has been rendered moot in light of the fact that claim 1 no longer recites “high density.”

It is clear from the specification, and from the original claims, that the “bio-reagent” and the “complimentary bio-reagent” can each be either an antigen or an antibody, as discussed, for example, on page 2, lines 16 – 25 of the instant specification. If, for example, the bio-reagent is

an antibody, then the complimentary bio-reagent is the antigen corresponding to that antibody. Likewise, if the bio-reagent is an antigen, then the complimentary bio-reagent is the antibody corresponding to that antigen. Accordingly, the terms “bio-reagent” and “complimentary bio-reagent” are neither vague nor indefinite. Reconsideration and withdrawal of this rejection are respectfully requested.

B. Claim 2

On page 5 of the Office Action, the Patent Office has rejected claim 2 for the alleged lack of antecedent basis for the term “the bulk solution.” This rejection has been rendered moot in light of the cancellation of claim 2. Reconsideration and withdrawal of this rejection are respectfully requested.

C. Claim 3

On page 5 of the Office Action, the Patent Office has rejected claim 3 for the alleged lack of antecedent basis for the term “that immunoreagent.” Applicant offers that this rejection has been overcome by the amendments to claim 3. Specifically, claim 3 now recites “first bio-reagent” instead of “that immunoreagent.” And, the term “first bio-reagent” has antecedent basis in claim 1. Reconsideration and withdrawal of this rejection are respectfully requested.

D. Claim 5

On page 5 of the Office Action, the Patent Office has rejected claim 5 for the alleged lack of antecedent basis for the term “the flowable phase.” Applicant offers that this rejection has been overcome by the amendments to claim 5. Specifically, claim 5 now recites “flowable component” instead of “flowable phase.” And, the term “flowable component” has antecedent basis in claim 1.

The Patent Office has also rejected claim 5 because the term “bio-polymer” is allegedly vague and indefinite. Further, the Patent Office has taken the position that the specification does not adequately define this term in order for one of ordinary skill in the art to understand what this term encompasses. Applicant respectfully disagrees. On page 3, lines 14 – 16 the specification provides a non-limiting example of a biopolymer, namely, dextran. Applicant offers that the ordinarily skilled artisan would therefore understand what the term “biopolymer” encompasses.

Accordingly, the term “biopolymer” recited in claim 5 is not vague and indefinite.

Reconsideration and withdrawal of the rejections of claim 5 are respectfully requested.

E. Claim 7

On page 5 of the Office Action, the Patent Office has rejected claim 7 because the phrase “the attraction of the flowable component is achieved by a membrane” is vague and indefinite. The Patent Office reasons that this phrase is rendered vague and indefinite because it is not clear how a membrane can achieve “attraction.” This rejection has been rendered moot, however, in light of the cancellation of claim 7. Reconsideration and withdrawal of this rejection are respectfully requested.

F. Claim 9

On page 5 of the Office Action, the Patent Office has rejected claim 9 for the alleged lack of antecedent basis for the terms “the assay,” “labeled antigen,” and “labeled antibody.” Applicant offers that this rejection has been overcome by the amendments to claim 9. Specifically, claim 9 now specifically recites that the *assay system*, as opposed to “the assay,” is either a competitive or non-competitive immunoassay. Further, claim 9 now recites that the first bio-reagent comprises a labelled antigen. Finally, claim 9 now recites that the second complimentary bio-reagent comprises an unlabelled antibody. And, all of the aforementioned terms have antecedent basis in claim 1. Reconsideration and withdrawal of the rejection of claim 9 is therefore respectfully requested.

G. Claim 19

The Patent Office has rejected claim 19 for the reasons set forth on page 5 of the Office Action. This rejection has been rendered moot in light of the cancellation of claim 19. Reconsideration and withdrawal of this rejection are respectfully requested.

VI. *The rejection of claims 1 – 7, 9, 10, and 19 under 35 U.S.C. §§ 102(b) and 102(e) should be withdrawn*

Claims 1 – 7, 9, 10, and 19 stand rejected as allegedly unpatentable under 35 U.S.C. § 102(b) over U.S. Patent No. 6,287,875 to Geisburg (hereinafter “Geisburg”) for the reasons set forth on pages 6 and 7 of the Office Action. The same claims stand rejected as allegedly

unpatentable under 35 U.S.C. § 102(e) over Publ. U.S. Appl. No. 2003/0207442 to Makovsky *et al.* (hereinafter “Makovsky”) for the reasons set forth on pages 8 and 9 of the Office Action.

Applicants respectfully traverse this art rejection.

Geisburg describes a device for the detection of at least one analyte in a sample solution comprising a solid support containing a sample application zone, a particle zone, and one or more signal ratios. The sample is applied to the sample application zone (3) and is wicked through the signal ratio areas (5), carrying with it the particles (11). *See* column 4, lines 37 – 42.

In addition, Geisburg discloses that the solid support may be porous (see column 8, lines 40 to 61) and hydrophilic or it may be fashioned from non-bibulous lateral flow material, which allows flow of a liquid through the membrane. Geisburg discloses that “the sample then moved through the porous elements of the strip by capillary action.” Col. 16, lines 56 – 58. This differs from the present invention which utilizes a system which includes a flowable component that rolls down the surface of the solid support, instead of diffusing into the support. Thus, Geisburg does not disclose the feature of “the solution which is denser than the buffer solution and which slowly rolls down the dip strip or planar surface during use” recited in claim 1. Instead, Geisburg’s system diffuses into the solid support and moves down as a result of capillary action.

Markovsky relates to a test device for detecting the presence of a residue analyte in a sample. It comprises a support strip and a sample absorbing matrix which absorbs an amount of the sample. Again, Markovsky teaches that the mobile phase composition is carried in the sample and flows together with the sample and that lateral capillary flow of the sample takes place between a first membrane end and a second membrane end. *See, e.g.*, paragraph 10. Thus, Makovsky does not disclose the feature of “the solution which is denser than the buffer solution and which slowly rolls down the dip strip or planar surface during use” recited in claim 1. The present invention does not rely on capillary action to enable samples to be brought in contact with each other. Instead, the mobile component flows down the surface of the strip.

Accordingly, neither Geisburg nor Makovsky anticipate claim 1 or any of the claims that depend from claim 1. Reconsideration and withdrawal of the rejection over Geisburg and Makovsky are respectfully requested.


VII. *The rejection under 35 U.S.C. § 103(a) of claim 8 does not apply to claim 22*

Claim 8 stands rejected as allegedly unpatentable under 35 U.S.C. § 103(a) by Geisburg or Makovsky in view of U.S. Patent No. 6,723,500 to Yu (hereinafter "Yu") for the reasons set forth on page 10 of the Office Action. Claim 8 has been cancelled. But, Applicants respectfully traverse this art rejection as it might apply to new claim 22.

As discussed above, neither Geisburg nor Makovsky disclose the feature of "the solution which is denser than the buffer solution and which slowly rolls down the dip strip or planar surface during use" recited in claim 1. And, even the combined teachings of Geisburg, Makovsky and Yu do not teach the claimed assay system. Yu discloses that "wicking" of the sample takes place. *See, e.g.*, claim 1, which recites the use of a "porous matrix." Furthermore, as understood by Applicant, Yu does not disclose the insertion of the strip into a buffer solution such that the sample rolls down the strip by gravity. Accordingly, the combined teachings of Geisburg, Makovsky and Yu do not render new claim 22 unpatentable.

In view of the above, it is believed that this application is now in condition for allowance, and a Notice thereof is respectfully requested. Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3620. All correspondence should continue to be directed to our address given below.

Respectfully submitted,



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